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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David L. Shelton

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EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/682,638	Applicant(s) SHELTON ET AL.	
	Examiner Jon M. Lockard	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/3/06</u> | 6) ☐ Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The amendment of 02 May 2006 has been entered in full. Claims 1 and 3 have been amended, claims 8-9 have been withdrawn, and claim 10 has been added. Therefore, claims 1-10 are currently pending and claims 1-7 and 10 are the subject of this Office Action.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 03 May 2006 has been considered by the examiner. Reference #25 has been considered to the extent of the abstract only, as the remainder of the reference is not in the English language.

Withdrawn Objections and/or Rejections

4. The objections to the Specification as set forth at pg 2-3 of the previous Office Action (mailed 02 February 2006) is withdrawn in view of Applicants amendment to the title (filed 02 May 2006).
5. The rejection of claims 1-7 under 35 U.S.C. § 112, 2nd Paragraph as set forth at pg 3 of the previous Office Action (mailed 02 February 2006) is withdrawn in view of amended claim 1, which now recites a step that relates back to the preamble of the claim, and amended claims 2 and 3, which no longer recite "suppressed or ameliorated" (filed 02 May 2006).

Maintained and/or New Objections and/or Rejections

Claim Rejections - 35 USC § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 2 recites the limitation "wherein resting pain" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1, from which claim 2 depends, does not recite "resting pain".

9. Claim 3 recites the limitation "wherein mechanically-induced pain" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1, from which claim 3 depends, does not recite "mechanically-induced pain".

10. With regards to the rejection of claims 2 and 3, it is suggested that an intervening claim which recites "The method of claim 1 wherein surgical pain consists of resting pain or mechanically-induced pain", or the like, would be remedial.

11. Claim 2 is further rejected as being indefinite for reciting the phrase "resting pain". At pg 24 ([0070]) the Specification teaches that "resting pain refers to pain occurring even while the individual is at rest as opposed to, for example, pain occurring when the individual moves or is subjected to other mechanical stimuli". However, at pg 59 ([0159]) the Specification teaches that resting pain was evaluated using a measure of weight bearing. Since the behavioral measure

Art Unit: 1647

of resting pain in this model involves a mechanical stimulus, i.e., weight bearing, it is unclear what is encompassed by this phrase in the claim.

12. Claim 3 is rejected as being indefinite for reciting the phrase “mechanically-induced pain”. At pg 24 ([0070]) the Specification teaches that “mechanically induced pain (interchangeably termed mechanosensory pain) refers to pain induces [sic] by a mechanical stimulus, such as the application of weight to a surface, tactile stimulus, and stimulation caused or associated with movement”. However, at pg 59 ([0159]) the Specification teaches that resting pain was evaluated using a measure of weight bearing. Since the behavioral measure of resting pain in this model involves a mechanical stimulus, i.e., weight bearing, it is unclear what is encompassed by this phrase in the claim.

13. Claim 3 is further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: mechanically-inducing pain. Therefore, it is unclear what additional method steps are intended to be encompassed by the claim.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1647

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ro et al. (Pain. 79:265-274, 1999; cited by Applicants) in view of Bennett et al. (European Journal of Neuroscience. 10:1282-1291, 1998), McMahon et al. (Nature Medicine. 1(8):774-780, 1995), and Brennan, T.J. (ILAR. 40(3):129-136, 1999; previously cited by Examiner).

17. Ro et al. teach administration of an anti-NGF antibody for the treatment of pain following constriction injury of the sciatic nerve (See entire document), which simulates a nerve injury and is an art-established model of neuropathic pain.

18. The reference of Ro et al. does not teach the administration of NGF antibodies for the treatment of post-surgical pain.

19. McMahon et al. teach that neutralization of endogenous NGF with trkA-IgG prevents hyperalgesia in a carrageenan-induced model of inflammation (See entire document).

20. Brennan teaches that the mechanisms for initiation and maintenance of pain after incision likely involve a combination of nerve injury, inflammation, pH changes, and central nervous system plasticity (See pg 133).

Art Unit: 1647

21. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the anti-NGF antibodies taught by Ro et al. for the treatment of post-surgical pain which would, in the absence of evidence to the contrary, ameliorate both resting pain and mechanically-induced pain.

22. The person of ordinary skill in the art would have been motivated to use the antibodies taught by Ro et al. to treat post-surgical pain because surgery is known to cause pain and it is obvious to treat the pain to alleviate discomfort in the patient.

23. The expectation of success is high since neutralizing endogenous NGF with an anti-NGF antibody has been shown to alleviate hyperalgesia in a nerve injury model as taught by Ro et al., neutralizing endogenous NGF with trkA-IgG immunoadhesion has been shown to alleviate hyperalgesia in a model of inflammation as taught by McMahon et al., and both nerve injury and inflammation are components of incisional (i.e., post-operative) pain as taught by Brennan.

24. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

25. Claims 1-7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ro et al. (Pain. 79:265-274, 1999; cited by Applicants) in view of Bennett et al. (European Journal of Neuroscience. 10:1282-1291, 1998), McMahon et al. (Nature Medicine. 1(8):774-780, 1995), and Brennan, T.J. (ILAR. 40(3):129-136, 1999) as applied to claims 1 and 10 above, and further in view of Hongo et al. (Hybridoma. 19(3):215-227, 2000; cited by Applicants) and Hoogenboom et al. (WO 93/06213, cited by Applicants).

Art Unit: 1647

26. The teachings of Ro et al., Bennett et al., McMahon et al., and Brennan are set forth above. None of the references teach anti-NGF antibodies that bind human NGF, antibodies that bind human NGF with a binding affinity of about 0.1 nM or less than about 0.1 nM. The references also do not teach human NGF antibodies or humanized NGF antibodies.

27. However, such antibodies as well as methods of making them were known in the art at the time of the invention. Hongo et al. teach humanized antibodies that bind human NGF with a binding affinity of about 0.1nM or less than about 0.1 nM (See pg 217, Table 1). Furthermore, Hoogenboom et al. teach how to make human antibodies (See entire document).

28. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Ro et al. and Bennett et al., McMahon et al., and Brennan as set forth above by using the antibodies taught by Hongo et al. and Hoogenboom et al. because humanized and human antibodies off the advantage of being more specific for humans and less likely to produce allergic or immune complex sensitivity (See Hoogenboom et al., pg 1, lines 1-22). The motivation to do so is also provided by Hoogenboom et al. who teach that human or humanized antibodies reduce the likelihood of inappropriate immune responses that interfere with therapy (See pg 1, lines 1-22). The person of ordinary skill in the art would have a reasonable expectation of success because the human or humanized antibodies would likely perform better for the reasons set forth above.

29. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Double Patenting

30. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/682,331 (US 2004/0228862 A1) for reasons of record set forth at pg 4-5 in the previous Office Action (mailed 02 February 2006).

32. Applicant's intention to resolve the issue at pg 7 of the response (filed 02 May 2006) is noted.

Art Unit: 1647

Summary

33. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Jon M. Lockard, Ph.D.
July 16, 2006

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud